

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

<b>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL No. 2327</b>
<b>THIS DOCUMENT RELATES TO WAVE 4 CASES ON EXHIBIT A TO PLAINTIFFS' MOTION</b>	<b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>

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**PLAINTIFFS' REPLY IN FURTHER SUPPORT OF  
DAUBERT MOTION TO PRECLUDE OR LIMIT OPINIONS OF  
DEFENSE EXPERT ELIZABETH MUELLER**

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## **LEGAL ARGUMENT**

### **DR. MUELLER'S GENERAL OPINIONS SHOULD BE PRECLUDED OR LIMITED**

Defendants' opposition to Plaintiffs' motion focuses primarily on statements made in Dr. Mueller's report, ignoring or minimizing fundamental concessions by Dr. Mueller in her sworn deposition testimony – concessions that should result in striking virtually all of her general opinions.

Another fundamental flaw in the Defendants' opposition is the focus on Dr. Mueller's qualifications as a practicing physician, which does not address the lack of objective or reliable methodologies to support the opinions. Dr. Mueller's opinions can be nearly reduced to a statement based on her own practice, and for her own needs in her own practice, the devices in question were properly designed and the warnings were adequate. That is not an adequate methodology since Dr. Mueller fails to reference or utilize any standards that can be objectively applied by others to test her opinions. Dr. Mueller does not even know the standards that were applied by Ethicon itself in the design and warnings, and thus cannot even apply those standards in offering her opinions.

First, with regard to the warning opinions, Defendants provide nothing to establish that Dr. Mueller applied any reliable methodology or standards in offering her conclusions, which are nothing more than net opinions. Experience with the product is not enough to overcome the fatal lack of objective, reliable criteria or method to forming these opinions – which were reportedly based on the IFU, surgeons monograph, and professional education material, of which Dr. Mueller candidly admitted she does not use, did not review, did not rely, and ultimately has no opinions.<sup>1</sup> Defendants attempt to circumvent these gaping holes in methodology by couching Dr. Mueller's

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<sup>1</sup> Pl. Mot. Ex. D at 70:12-21, 71:10-16, 243:22-245:2.

warnings opinions as risks that are “commonly known.”<sup>2</sup> Plaintiffs’ motion did—and does—seek to exclude Dr. Mueller from discussing whether certain risks were commonly known in the medical community. Defendants attempt to argue in its response brief that Dr. Mueller will not be offering opinions as to what should or should not be included in the IFU. However, within the same breath, Defendants go on to state that Dr. Mueller would be offering the opinion “that risks that are within the common knowledge of physicians are risks that would not, as a matter of logic, be included in an IFU.”<sup>3</sup> Furthermore, Dr. Mueller’s expert report specifically opines on the adequacy of Ethicon’s IFU, Surgeon’s Monograph, and professional educational materials, even though she had not reviewed or relied on these documents.<sup>4</sup> In essence, even though they claim otherwise, Defendants argue that Dr. Mueller should be allowed to opine that the IFU is accurate and sufficient because, to the extent any risks were not included, those risks are commonly known to the medical community.<sup>5</sup> But, as Plaintiffs set forth in their motion, Dr. Mueller has clearly admitted that she has no knowledge or interest in what risks are included in the IFU. As such, Dr. Mueller should be precluded from testifying that any certain risk was commonly known in the medical community. Allowing her to provide such speculative testimony would allow Ethicon to argue that it had no duty to warn of those risks.

Second, with regard to design and mesh properties opinions, Defendants ignore Dr. Mueller’s concession that she completely lacks knowledge regarding the appropriate pore size, weight, or cut of the TVT and TVT-O sling devices. Specifically, as Plaintiffs’ motion sets forth, Dr. Mueller testified that mesh properties are out of her purview. As such, Dr. Mueller should be precluded from opining on mesh design and properties.

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<sup>2</sup> Defs’ Mem. at 2-6.

<sup>3</sup> Defs’ Mem. at 6.

<sup>4</sup> As Plaintiffs’ motion argues, Dr. Mueller rescinded these opinions during her sworn testimony.

<sup>5</sup> Defs’ Mem. at 2-6.

### **CONCLUSION**

For all of the foregoing reasons, in addition to the arguments set forth in Plaintiffs' motion, Plaintiffs' *Daubert* motion to preclude or limit the opinions of Dr. Mueller should be granted.

Dated: May 4, 2017

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that I filed the foregoing document on May 4, 2017, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

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